DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00P–1548]

Determination That Cyclosporine Capsules USP, 50 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that cyclosporine capsules USP (Neoral Soft Gelatin Capsules), 50 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for cyclosporine capsules USP, 50 mg.

FOR FURTHER INFORMATION CONTACT: Paul C. Varki, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

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The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products with Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

Cyclosporine capsules USP, 50 mg, are the subject of NDA 50–715. On July 14, 1995, Sandoz, Inc. (now Novartis), obtained approval to market the 25-, 50-, and 100-mg capsules. Novartis has never marketed the 50-mg capsules.

On September 29, 2000, Lachman Consultant Services, Inc., submitted a citizen petition (Docket No. 00P–1548/CP1) under 21 CFR 10.30 to FDA requesting that the agency determine whether cyclosporine capsules USP, 50 mg, were withdrawn from sale for reasons of safety or effectiveness. FDA has determined that, for purposes of § 314.161(a) and (c), never marketing an approved drug product is equivalent to withdrawing the drug from sale.

FDA has reviewed its records and, under § 314.161, has determined that Novartis' decision not to market cyclosporine capsules USP, 50 mg, was not due to concerns about safety or effectiveness of the product. Accordingly, the agency will maintain cyclosporine capsules USP, 50 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to cyclosporine capsules USP, 50 mg, may be approved by the agency.

Dated: 7/6/01
July 6, 2001.

Margaret M. Dotzel,
Associate Commissioner for Policy.

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